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CIBA Vision® Corporation
11460 Johns Creek Parkway
Duluth, GA USA 30097

FreshLook® sphere, FreshLook® Toric and FreshLook® Progressives (nelfilcon A) One Day Color Soft Contact Lenses

510(k) Summary of Safety and Effectiveness

510(k) Summary K050213

1. Submitter Information:

Company: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Contact Person: Angela L. Bunn, RAC
Senior Regulatory Affairs Specialist,
Fashion Wear and Specialty Lenses
Global Regulatory Affairs

Telephone: 678-415-3784
FAX: 678-415-3454

Date Prepared: 10, February 2005

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: FreshLook®, FreshLook® Toric and FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses
- Classification Name: Daily Wear Soft (hydrophilic) Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device(s):

Lens Material: CIBA Vision's Focus® DAILIES® (nelfilcon A) One Day Contact Lens

Clear lenses (spherical & toric):	K943487
VISITINT® lenses:	K984273
Manufacturing Change-Surfactant Additive:	K010636

Multifocal Design: CIBA Vision's Focus® DAILIES® Progressives (nelfilcon A) One Day

Visitint lenses:	K003826

Print Process/Use of Color Additives:

FreshLook® (phemfilcon A) soft contact lenses	P830037

4. Description of Device:

FreshLook® (nelfilcon A) Soft (hydrophilic) One Day Color Contact Lenses are available in a spherical lens design, FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses are available in a multifocal lens design and FreshLook® Toric (nelfilcon A) One Day Color Contact Lenses are available in a toric design. The lenses are to be prescribed for single use daily disposable wear.

The FreshLook®, FreshLook® Toric and FreshLook® Progressives (nelfilcon A) One-Day Colors Contact Lens are daily wear soft contact lenses intended for single use daily disposable wear. The FreshLook One-Day Colors contact lens is a spherical soft contact, FreshLook One-Day Colors Toric lenses have a double thin zone design, and the FreshLook One-Day Colors Progressives lens is a progressive aspheric simultaneous vision soft contact lens. A constant near power profile is incorporated into each Progressive lens across the full range of distance powers. The near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted toward distance. The continuous changes in power across the surface of the lens allow patients requiring a reading addition of up to +3.00 diopters to see clearly at far, intermediate and near distances.

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are clear or tinted from edge to edge for visibility purposes with the color additive copper phthalocyanine (CuP). FreshLook® (nelfilcon A) One Day Color Contact Lenses are printed with an intermittent coating containing a combination of the following approved pigments: iron oxides, titanium dioxide, [phthalocyaninato (2-)] copper, chromium oxide and carbazole violet.

Lenses are supplied sterile in foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution. The package storage saline may contain up to 0.02% Poloxamer 108.

The physical properties of the lenses are:

- Refractive Index: 1.38 (hydrated)
- Center Thickness: 0.09 to0.17 mm (0.10 at -3.00D; 0.15 at +3.00D) (varies with power)
- Light Transmittance: Clear ≥ 97%
- Visitint 96% (approx)
- Oxygen Permeability (Dk): 26×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) at 35° C (Fatt corrected)
- Water Content: 69% by weight in normal saline

5. Indications for Use:

FreshLook® spherical and FreshLook® Toric (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes. The FreshLook® spherical and FreshLook® Toric (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity. The FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

The FreshLook® (nelfilcon A) One Day Color Contact Lenses are to be prescribed for single-use Daily Disposable Wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single-use.

6. Description of Safety and Substantial Equivalence

6.1 Comparison to Predicate Device (s):

- Lens Material [Predicate Lens current DAILIES® (nelfilcon A)]:
  Lens material, chemical composition, formulation, manufacturing process, packaging and the sterilization method and cycle remain unchanged from the descriptions previously provided in cleared Premarket Notifications 510(k) K963487, K984273, K992446, K003826, K010636.

- Lens Design:
  No change to established spherical, toric or multi-focal lens designs.

FreshLook® sphere, FreshLook® Toric and FreshLook® Progressives (nelfilcon A) One Day Color Soft Contact Lenses

510(k) Summary of Safety and Effectiveness

Table 1: Comparison to CIBA Vision's Predicate Device

	Predicate Device	
	DAILIES® (nelfilcon A) One Day Contact Lens	FreshLook® (nelfilcon A) One Day Color Contact Lens
Lens Material:	nelfilcon A	nelfilcon A
Material Classification:	FDA Group 2 (> 50% H_2O, nonionic polymer)	FDA Group 2 (> 50% H_2O, nonionic polymer)
Water Content:	69%	69%
Light Transmittance (clear lenses):	99%	97%
Oxygen Permeability (Dk, Coulometric):	~25 barrers	~25 barrers
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without Copper Phthalocyanine	With or without Copper Phthalocyanine
Manufacturing Method:	Full Mold Cast Lightstream Technology	Full Mold Cast Lightstream Technology 3-in-1 Print Technology
Lens Design:	Spherical and/or Multi-focal	Spherical and/or Multi-focal
Sterilization:	Steam sterilization, Validated autoclave	Steam sterilization, Validated autoclave
Packaging:	Blister Pack	Blister Pack
Package Storage saline solution	Phosphate-acetate buffered saline	Phosphate-acetate buffered saline

6.2 Non-clinical Testing:

Results from a series of physical/chemical tests confirm that FreshLook® (nelfilcon A) One-Day Colors contact lenses were equivalent and within established specifications for the lenses. Preliminary shelf-life studies confirm the lenses are stable and compatible with the container packaging system, and have established a product shelf-life that will be extended over time following successful completion of testing intervals. Successful results from in-vivo and in-vitro toxicology tests confirm the lenses remain non-toxic and biocompatible with the ocular environment.

6.3 Clinical Testing:

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the FreshLook® One Day Color (nelfilcon A) Soft Contact Lenses. This determination was based on the following:

- The FreshLook® One Day Color (nelfilcon A) Soft Contact Lenses were demonstrated to be substantially equivalent to the predicate Dailies® (nelfilcon A) Soft Contact Lenses (K963487, K984273, K992446, K003826, and K010636).

- The FreshLook® One Day Color (nelfilcon A) Soft Contact Lenses were demonstrated to be substantially equivalent to the predicate FreshLook® Color, FreshLook ColorBlends®, FreshLook Dimensions™ and FreshLook Radiance™ (phemfilcon A) and the print technology and use of approved color additives under P830037.

7. Substantial Equivalence

FreshLook® One Day Color contact lenses made with currently approved contact lens color additives utilizing the current 3-in-1 print technology used in FreshLook® (phemfilcon A) products is equivalent and within established specifications for the lens. The lenses maintain clinical performance expectations, established physical/chemical characteristics, and are stable and biocompatible with the ocular environment. Any difference which may exist between lenses made with or without the color additives does not adversely effect the established performance characteristics and safety and effectiveness profile of the device.

The information provided in this submission established that the FreshLook ® One Day Color (nelfilcon A) Soft Contact Lenses in multiple designs and multiple colors and effects is equivalent in optical, chemical and physical properties of the predicate devices and does not rise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate devices of Dailies® and FreshLook® Colors, FreshLook ColorBlends®, FreshLook Dimensions™ and FreshLook Radiance™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2005

CIBA Vision Corporation
c/o Paul G. Oris
Head, Global Regulatory Affairs
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K050213
Trade/Device Name: FreshLook® (nelfilcon A) One Day Color Soft Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: MVN
Dated: December 29, 2004
Received: January 31, 2005

Dear Mr. Oris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

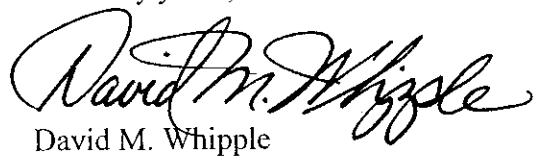
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name(s): **FreshLook® Sphere, FreshLook® Toric and FreshLook® Progressives (nelfilcon A) One Day Color Contact Lens**

Indications For Use:

FreshLook® spherical and FreshLook® Toric (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes. The FreshLook® spherical and FreshLook® Toric (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia or hyperopia) and/or presbyopia in not-aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity. The FreshLook® Progressives (nelfilcon A) One Day Color Contact Lenses also act to enhance or alter the apparent color of the eye.

The FreshLook® (nelfilcon A) One Day Color Contact Lenses are to be prescribed for single-use Daily Disposable Wear. The lenses are not intended to be cleaned or disinfected and should be discarded after a single-use.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K050213

Prescription Use: X **or** **Over the Counter Use** ☐